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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,003	08/29/2001	Nobuko Yamamoto	B588-023	9023
26272 7590 07/21/2009 COWAN LIEBOWITZ & LATMAN P.C. JOHN J TORRENTE 1133 AVE OF THE AMERICAS NEW YORK, NY 10036				
EXAMINER SHERR, CRISTINA O				
ART UNIT		PAPER NUMBER		
3685				
MAIL DATE		DELIVERY MODE		
07/21/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

09/942,003

Applicant(s)

YAMAMOTO ET AL.

Examiner

CRISTINA SHERR

Art Unit

3685

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 1, 7-11, 17-21, 24, 27-28, 31, 34-37, 41-42, 45, 48-51, 53, 57-58, and 60-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25, 33, 39 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 1, 7-11, 17-21, 24-25, 27-28, 31, 33-37, 39, 41-42, 45, 47-51, 53, 57-58, and 60-66

### **DETAILED ACTION**

1. This Office Action is in response to Applicant's Amendment filed April 2, 2009. Claims 1, 7-11, 17-21, 24-25, 27-28, 31, 33-37, 39, 41-42, 45, 47-51, 53, 57-58, and 60-66 are currently pending in this case. Claims 25 and 39 are currently amended. Claims 25, 33, 39, and 47 are currently under examination.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 6, 2009 has been entered.

#### ***Election/Restrictions***

3. Applicant's election without traverse of Species D -- claims 25, 33, 39, and 47 -- in the reply filed on April 2, 2009 is acknowledged.

#### ***Response to Arguments***

4. Applicants' arguments filed January 6, 2009 have been fully considered but they are not persuasive.

5. Applicants argue, regarding claim 25 and 39, as currently amended, that nothing in the cited prior art, teaches, discloses or suggests, wherein "plurality of spots of different DNA probes are arranged on the DNA array so that the DNA array presents a different hybridization pattern depending on a different personal DNA, each of the spots

indicates presence or absence of a target gene arrangement by presence or absence of reaction and the hybridization pattern is a two-dimensional binary pattern indicated by the presence or absence of the reaction at the spots.”

6. Examiner respectfully disagrees and notes that the amended portion of the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Because the said amendments to the claims do not appear to have support in the specification, the newly-added language does not serve to further distinguish the claims from the prior art.

***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 39 and 47 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Based on Supreme Court precedent (See also *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) and recent Federal Circuit decisions, a §101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In addition, the tie to a particular apparatus, for example, cannot be mere extra-solution activity. See *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

9. Claim 39 recites, *inter alia*, "providing a storage means", "acquiring layout information", "generating authentication information", and "collating the authentication information", while remaining silent with respect to who or what performs these steps. For this reason, in dependent claim 39 and its dependent claim 47 are rejected under 35 U.S.C. 101.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 25, 33, 39, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the amended portion of claims 25 and 39 contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere does the specification appear to disclose wherein the hybridization pattern is a two-dimensional binary pattern indicated by the presence or absence of the reaction at the spots."

12. For these reasons, independent claims 25 and 39 and their dependent claims 33 and 47 are rejected under 35 U.S.C. 112, first paragraph.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 25 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Specifically, claim 25 recites "controlling means for executing a process comprising the steps of:

(i) generating authentication information on the basis of the layout information acquired by said acquisition means; and

(ii) collating the authentication information with the registration information as a reference stored in said storage means, and making authentication"

16. It is unclear whether the generating and authenticating are steps of the process being executed or steps in the controlling the process. Note that an essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed. *In re Zletz*, 13 USPQ2d 1320 (Fed. Cir. 1989) Therefore, independent claim 25 and its dependent claim 33 are rejected under 35 U.S.C. 112, second paragraph.

17. It has been held that a claim that recites both an apparatus and a method for using said apparatus is indefinite under section 112, paragraph 2, as such a claim is not sufficiently precise to provide competitors with an accurate determination of the 'metes and bounds' of protection involved. *IPXL Holdings LLC v. Amazon.com Inc.*, 77 USPQ2d 1140 (CA FC 2005); *Ex parte Lyell*, 17 USPQ2d 1548 (B.P.A.I. 1990). Also, a

single claim which purports to be both a product or machine and a process is ambiguous and is properly rejected under 35 USC 112, second paragraph, for failing to particularly point out and distinctly claim the invention. *Ex Parte Lyell*, 17 USPQ2d 1548 (B.P.A.I. 1990).

18. In this case, claim 25 recites "controlling means for executing a process comprising the steps of:

(i) generating authentication information on the basis of the layout information acquired by said acquisition means; and

(ii) collating the authentication information with the registration information as a reference stored in said storage means, and making authentication"

19. Since claim 25 recites both a an apparatus and method for the use of that apparatus, claim 25 and its dependent claim 33 are rejected under 35 U.S.C. 112, second paragraph.

#### ***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 25, 33, 39, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Black (US 6,307,956B1) in view of Yguerabide et al (US 6,586,193) further in view of Lockhart et al (US 6,344,316).

22. Regarding claims 25 and 39 –



23. Black discloses an identity verification system, method, and apparatus that employ biometric technology for identity verification (e.g. col 4 ln 18-28). The biometric properties employed include, but are not limited to DNA (e.g. col 4 ln 30-40). Said system, method and apparatus make a "match" or "no match" decision and issues and certify or do not certify the user. (e.g. col 4 ln 55-65). Further, Black discloses recording and storing the layout information as either digital or magnetic information (e.g. col 4 ln 20-30). Further, Black discloses the use of cell capture/analysis sensors for use in identifying DNA (e.g. col 7 ln 50-60).

24. Although Black does not specifically reference recording the DNA layout information by arranging probe layouts in row and column directions, it would be a predictable result to that an array of immobilized single-stranded DNA (ssDNA) could be arrayed as rows and columns or any other logical manner (e.g. col 25 ln 25-35). *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

25. Further, although the references do not specifically disclose wherein each of the plurality of different DNA probes is indicative of a person's MHC genes or a person's SNPs by whether or not each of the plurality of different DNA probes is reactive or non reactive to that person's DNA, examiner takes Official Notice that both MHC genes and SNP genes as well as the reagents that identify them are old and well-known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include, inter alia, reagents to both or either SN\_ genes or MHC genes among the probes used in the instant application. We direct attention to, for example "An historical introduction to the Mhc" (Peter Hjelmstron, 1996 at

<http://depts.washington.edu/rhwlab/resMat/dq/history.html>) which discloses research in the area of MHC genes as far back as 1916, and to SNP Fact Sheet (Human Genome Project Information at [http://www.ornl.gov/sci/techresources/Human\\_Genome/faq/snps.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml)) referencing SNP gene research from 1998 and earlier.

26. Further, Yguerabide does disclose reacting a DNA array in which a plurality of DNA probes corresponding to plural kinds of genes are arranged in a predetermined order, with a gene obtained from a given person (e.g. col 11 ln 30-50). It would be obvious to one of ordinary skill in the art to use an arrangement can in conjunction or in combination with Black in order to issue an authentication certificate using, *inter alia*, a hybridization pattern.

27. Neither Black nor Yguerabide disclose attaching the reacted DNA array to a base of the authentication certificate. However, Lockhart (at, e.g., col 107 ln 4-12) provides such a disclosure. Such an arrangement can obviously be used in conjunction or in combination with Black and Yguerabide by one of ordinary skill in the art motivated by the need to issue a unique authentication certificate.

28. Regarding claims 33 and 47 –

29. Black does not disclose wherein the DNA array comprises the DNA probes associated with major histocompatibility complex antigens and single nucleotide polymorphisms. Yguerabide, however, does. (col 104, ln 5-28, col 104 ln 32-37)

30. As above, it would be obvious to one of ordinary skill in the art for such an arrangement to be used in conjunction or in combination with Black in order to issue a unique authentication certificate.

***Conclusion***

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRISTINA SHERR whose telephone number is (571)272-6711. The examiner can normally be reached on 8:30-5:00 Monday through Friday.

32. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Calvin L. Hewitt, II can be reached on (571)272-6709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

33. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRISTINA OWEN SHERR

Application/Control Number: 09/942,003  
Art Unit: 3685

Page 10

Examiner  
Art Unit 3685

/Calvin L Hewitt II/  
Supervisory Patent Examiner, Art Unit 3685